Chapter 11

England & Wales

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1 General - Medicinal Products

1.1 What laws and codes of practice govern the advertising of medicinal products in the UK?

The advertising of medicinal products in the UK is controlled by a combination of legislation and codes of practice.

There are two principal sets of regulations implementing the relevant Community provisions: the Medicines (Advertising) Regulations 1994 (SI 1994/1932); and the Medicines (Monitoring of Advertising) Regulations 1994 (SI 1994/1933), (together, the 'Regulations'). Further provisions are set out in Part VI of the Medicines Act 1968. The Medicines and Healthcare Products Regulatory Agency (MHRA) supervises the advertising of medicinal products on behalf of the Health Ministers/Licensing Authority. The Regulations are supplemented by guidelines published by the MHRA. The current version is called "The Blue Guide - Advertising and Promotion of Medicines in the UK" and was published in November 2005. A revised version is expected to come into force in July 2012.

Control by the MHRA is supplemented by industry Codes of Practice and these Codes provide the real day-to-day control over the advertising of medicines. The Codes have been developed in consultation with the MHRA and are consistent with the legal requirements, while in some cases going beyond them. The Association of the British Pharmaceutical Industry Code of Practice (the ABPI Code), administered by the Prescription Medicines Code of Practice Authority (PMCPA), governs the advertising of prescription-only medicines. The latest version of the ABPI Code came into operation on 1 January 2012. The Proprietary Association of Great Britain (PAGB) Consumer Code governs the advertising of over-the-counter medicines to the general public and the PAGB Professional Code governs the advertising of over-the-counter medicines to persons qualified to prescribe or supply.

In addition to the controls on medicines, in principle other general legislation may be relevant, such as the Trade Descriptions Act 1968. Commercial practices (including advertising) relating to consumer goods are subject to a series of laws on trading of consumer goods, including the Consumer Protection from Unfair Trading Regulations 2008/1277 (business-to-consumer practices) and the Business Protection from Misleading Marketing Regulations 2008/1276 (business-to-business practices).

1.2 How is "advertising" defined?

"Advertisement" is not fully defined in the Regulations, which refer back to the definition in section 92 of the Medicines Act 1968. This defines the term broadly, but not helpfully, to include "every form of advertising, whether in a publication or by the display of any notice, or by means of any catalogue, price list, letter (whether circular or addressed to a particular person) or other document, or by words inscribed on any article…or in any other way".

However, the Regulations exclude from the definition of "advertising" reference materials, factual informative statements or announcements, trade catalogues and price lists, provided that these contain no product claims.

The ABPI Code does not define "advertising" but does define "promotion", which is not different in principle. This covers "any activity undertaken by a pharmaceutical company or with its authority which promotes the prescription, supply, sale or administration of its medicines" (Clause 1.2).

The Court of Justice of the European Union (CJEU) has clarified the definition of advertising, and the persons subject to EU advertising rules, in Cases C-421/07 *Damgaard*, C-62/09 *ABPI*, and C-316/09 *MSD*. In all cases, the CJEU recognised that Article 86(1) of Directive 2001/83/EC (the Directive) provides a definition of advertising that focuses on the purpose of the message. The fundamental criterion for separating advertising from mere information lies in the objective pursued, i.e. if the intention is to promote the prescription, supply, sale or consumption of medicinal products, then it is advertising for the purposes of the Directive. The Directive does not require a message to be disseminated by a person linked to the manufacturer and/or seller of the medicinal product or to be disseminated in the context of commercial or industrial activity in order for it to be held to be advertising. (In the *ABPI* case, however, the CJEU ruled that the Directive concerns primarily promotional activities carried out by the pharmaceutical industry and the prohibitions, for example, in relation to the provision of financial inducements, do not apply to national authorities pursuing public health policy, including any policy on the public expenditure on pharmaceuticals.) The dissemination of information which is a faithful reproduction of the approved package leaflet or summary of product characteristics of a medicinal product is unlikely to be considered advertising, although in the *MSD* case the CJEU held that the selection, manipulation or rewriting of any such information can likely only be explained by an advertising purpose.

1.3 What arrangements are companies required to have in place to ensure compliance with the various laws and codes of practice on advertising, such as "sign off" of promotional copy requirements?

Companies should make sure that all staff involved in promotion

are trained on the ABPI Code. Although companies may have different internal procedures and guidelines for reviewing material, promotional material must not be issued unless its final form has been certified by two persons on behalf of the company. One of the two persons should be a registered medical practitioner or a registered pharmacist. The second person certifying must be an appropriately qualified person or senior official of the company or an appropriately qualified person whose services are retained for that purpose. The following materials must be certified in a similar manner: (i) educational material for the public or patients issued by companies which relates to disease or medicines, but is not intended as promotion for those medicines; (ii) material relating to working with patient organisations; (iii) material prepared in relation to joint working between the NHS and the pharmaceutical industry; (iv) material relating to patient support programmes involving the provision to health professionals of items to be passed on to patients; and (v) non-promotional material for patients or health professionals relating to the provision of medical and educational goods and services issued by companies, with the difference that one of the persons certifying must be a registered medical practitioner, or, in the case of a product for dental use only, a registered medical practitioner or a dentist. Material which is still in use must be recertified at intervals of no more than two years. Certificates and accompanying material must be retained for at least three years after the final use of the material. Companies must have a scientific service to compile and collate all information issued or received from any other source about the medicines they market.

1.4 Are there any legal or code requirements for companies to have specific standard operating procedures (SOPs) governing advertising activities? If so, what aspects should those SOPs cover?

There are no legal requirements for companies to have specific SOPs. The ABPI Code includes a section on "Guidelines on company procedures relating to the code of practice". These guidelines provide that in order to assist with compliance, companies should have a comprehensive set of SOPs covering all aspects of the ABPI Code. SOPs should set out high standards and companies and are expected to ensure that relevant staff are trained on their content. The guidelines require pharmaceutical companies to have written documents setting out the representatives' instructions on the application of the ABPI Code to their work and a written document that sets out their policies on meetings and hospitality and the associated allowable expenditure.

1.5 Must advertising be approved in advance by a regulatory or industry authority before use? If so, what is the procedure for approval? Even if there is no requirement for prior approval in all cases, can the authorities require this in some circumstances?

The Regulations do not require the advance approval of all advertising. However, the MHRA has the power under SI 1994/1933 to issue a notice requiring a marketing authorisation holder to supply copies of advertisements prior to publication and not to use those advertisements until they have been approved. It is a criminal offence to fail to comply with such a notice. In any event, pre-use vetting is usually requested in the following instances: (i) where a newly licensed product subject to intensive monitoring is placed on the market; (ii) where a product is a reclassified product, for example, Prescription-Only (POM) to Pharmacy (P); or (iii) where previous advertising for a product has breached the Regulations. Pre-use vetting may also be requested as a result of a major new indication for use of the product or where there are safety concerns. Since 2005, all new active substances granted Marketing Authorisations (MAs) in the UK have had their promotional materials vetted. A request for vetting of promotional material is usually triggered following the presentation of an application for an MA to the Commission on Human Medicines (CHM). The MHRA Advertising Unit will write to the company requesting their agreement to submit promotional material for vetting. MHRA guidance suggests that the duration of the vetting is commonly around six months, but this may be reduced or extended depending on the quality of the initial advertising material submitted and other relevant factors. Promotional material may be submitted for vetting once the SPC has been finalised and after undergoing a full set of internal quality control. Information on the target audience should be included (MHRA MAIL 152 of November/December 2005).

It is also open to companies to seek guidance from the MHRA on proposed advertisements.

The ABPI Code does not require any prior approval for the advertising of prescription-only medicines, but again guidance can be sought prior to publication.

In the case of over-the-counter medicines, the procedure depends upon the intended audience. The PAGB Consumer Code requires prior approval. Companies must submit draft advertisements to its secretariat for approval prior to use. However, this requirement does not apply to advertisements aimed at persons qualified to prescribe or supply medicines, or their employers, as these are caught by the PAGB Professional Code.

1.6 If the authorities consider that an advertisement which has been issued is in breach of the law and/or code of practice, do they have powers to stop the further publication of that advertisement? Can they insist on the issue of a corrective statement? Are there any rights of appeal?

The MHRA has the power under SI 1994/1933 to issue notices prohibiting the publication of specified advertisements. If it notifies a company that it is minded to consider an advertisement to be in breach of the Regulations, the company has the right to make written representations to an Independent Review Panel, which gives advice to the MHRA. If the MHRA issues a final notice determining that an advertisement is in breach, the company has no further right of appeal against the notice and will commit a criminal offence if it publishes the advertisement. The company may also be required to publish a corrective statement.

While there is no appeal mechanism, the MHRA states that it is open to the company to challenge the legality of a notice by means of judicial review. In practice, this is likely to be unsuccessful, unless the Panel's procedure was procedurally unfair in some way.

1.7 What are the penalties for failing to comply with the rules governing the advertising of medicines? Who has responsibility for enforcement and how strictly are the rules enforced? Are there any important examples where action has been taken against pharmaceutical companies? To what extent may competitors take direct action through the courts?

The Regulations create a number of offences for failing to comply with the relevant Community provisions. Enforcement is by the Enforcement Division of the MHRA. In most cases, a person (including a company) who contravenes the legislation faces a fine of up to £5,000 per offence if the matter is dealt with by the

Magistrates Court. If the matter is dealt with by the Crown Court, there is no statutory maximum fine, and the Court will impose a higher figure in the case of a serious breach. In addition (or alternatively), a period of up to two years' imprisonment may be imposed.

Prosecutions for advertising offences are extremely rare. Recent prosecutions for illegal advertising do not relate to advertising activities addressed to healthcare professionals, but rather to products that are claimed to have medicinal properties but which are not authorised as medicines, or to advertising to the general public of POMs via the Internet or otherwise. The MHRA prefers to resolve complaints quickly and informally, with companies agreeing to take voluntary action to amend their advertising and, in some cases, to issue a corrective statement. Details of cases resolved informally are posted on the MHRA's website.

In the case of a failure to comply with the rules on samples, or the soliciting or accepting inducements by health professionals, the matter must be dealt with by the Magistrates Court and the maximum penalty is a fine of £5,000 per offence.

Under the ABPI Code, a decision is first made by the PMCPA's internal Panel, although there is a right to appeal to a Board consisting of representatives of industry of the medical profession and independent members (who will form a majority) chaired by an independent lawyer. Administrative charges are payable when a company is found in breach of the ABPI Code (£3,000 per matter for ABPI member companies, or £11,000 if the matter is unsuccessfully appealed). The Authority also has the power in serious cases to require an audit of a company's promotional procedures, or to suspend or expel the company from the ABPI.

The PAGB does not impose any financial sanction, but a company may be expelled from the PAGB if it has failed to comply with the ABPI Code.

Generally it is not usual for competitors to take direct action through the courts, although they can make complaints to the MHRA, PMCPA and PAGB. Legal proceedings by companies would only be possible in the case of an action based on defamation, slander of goods or an infringement of trade mark rights. There is no unfair competition statute that provides a ready basis for a complaint.

1.8 What is the relationship between any self regulatory process and the supervisory and enforcement function of the competent authorities? Can, and, in practice, do, the competent authorities investigate matters drawn to their attention that may constitute a breach of both the law and any relevant code and are already being assessed by any self-regulatory body? Do the authorities take up matters based on an adverse finding of any self-regulatory body?

The relationship between the self-regulatory process administered by the PMCPA and the supervisory and enforcement function of the competent authority, the MHRA, is set out in a Memorandum of Understanding between the two bodies and the ABPI. The two systems are regarded as "complementary and synergistic", but the self-regulatory system does not oust the jurisdiction of the MHRA. Both bodies can hear complaints from whatever source, save that the MHRA would normally refer inter-company complaints to the PMCPA to deal with and may refer other complaints to the PMCPA with the consent of the complainant. The MHRA will routinely decline to investigate cases where it is aware that these are under investigation by a self-regulatory body, but reserves the right to take action if serious public health concerns are raised or if self-regulation fails. Self-regulation may be treated as having failed if the sanctions imposed by a self-regulatory body do not seem to deter a company from committing further material breaches of the rules. It is possible that material pre-vetted and approved by the MHRA might subsequently be ruled by the PMCPA as in breach of the ABPI Code. The MHRA regularly reviews information on the PMCPA website about the consideration of current cases and may investigate the case further when the PMCPA proceedings are completed. To date, there have been no prosecutions by the MHRA following adverse findings of the PMCPA.

1.9 In addition to any action based specifically upon the rules relating to advertising, what actions, if any, can be taken on the basis of unfair competition? Who may bring such an action?

UK legislation does not create a separate offence of unfair competition. Setting aside breach of the advertising rules, there is the option of taking an action based on trade mark law, passing off or trade libel. A trade mark infringement action may be brought by the owner of the trade mark which has been infringed. A passing off action may be brought by a party whose goods are being misrepresented as the goods of another party, provided the party in question can show sufficient goodwill in the name of the product and such actions lead to a misrepresentation that causes damage. A trade libel action may be brought by a trading corporation or company whose reputation in the way of its trade or business is damaged.

2 Providing Information Prior to Authorisation of Medicinal Product

2.1 To what extent is it possible to make information available to health professionals about a medicine before that product is authorised? For example, may information on such medicines be discussed, or made available, at scientific meetings? Does it make a difference if the meeting is sponsored by the company responsible for the product? Is the position the same with regard to the provision of off-label information (i.e. information relating to indications and/or other product's variants not authorised)?

Regulation 3 of SI 1994/1932 (reflected in Clause 3 of the ABPI Code) states that no person may issue an advertisement for a medicinal product which does not have a marketing authorisation or a traditional herbal registration.

However, it is possible to discuss research concerning unlicensed medicines at genuine scientific meetings, provided neither the content nor the tone of the discussions appears designed to promote use of the product, but is merely informing the audience of new scientific knowledge and encouraging a legitimate exchange of scientific information. This is possible even if a pharmaceutical company is sponsoring the meeting.

It is not possible for companies to display information about unlicensed medicines at such meetings, but they may make scientific information available at the request of delegates. Companies must not, however, solicit such requests.

Clause 3 of the ABPI Code sets out special rules for the promotion of medicines at international meetings taking place in the UK. Where these meetings are truly international and of high scientific standing with a significant proportion of attendees from outside the UK, it is possible to display information on medicines which are not authorised in the UK, but are authorised in at least one other major industrialised country. This is endorsed in the MHRA Guidance. The position is the same regarding the provision of off-label information.

2.2 May information on unauthorised medicines be published? If so, in what circumstances?

Information of genuine scientific interest which is not promotional may be published. If the publication has been sponsored by a pharmaceutical company, the fact of sponsorship must be clearly indicated.

2.3 Is it possible for companies to issue press releases about medicinal products which are not yet authorised? If so, what limitations apply?

It is possible to issue press releases to both professional and general audiences, provided that the releases concern a matter of legitimate scientific interest (for example, the results of a pivotal clinical trial) and that they are not promotional in tone. For example, the trade name should be used in moderation and sweeping claims should not be made. The tone and content must be accurate, factual and balanced.

2.4 May such information be sent to health professionals by the company? If so, must the health professional request the information?

Holders of a licence permitting the manufacture, importation and/or distribution of unlicensed medicines can issue price lists to healthcare professionals provided no product claims are included. The MHRA has advised that any price list supplied should only consist of a basic line listing providing the following information: reference number; medicinal product name (British-approved name or equivalent); dosage form; strength; pack size; and price.

Catalogues and circular letters may only be sent to healthcare professionals on receipt of a *bona fide* unsolicited order. The company must not encourage health professionals to make such a request. Ideally such a request should be channelled through the company medical information department, rather than via sales and marketing personnel.

2.5 How has the ECJ judgment in the Ludwigs case, Case C-143/06, permitting manufacturers of non-approved medicinal products (i.e. products without a marketing authorisation) to make available to pharmacists price lists for such products (for named-patient/compassionate use purposes pursuant to Article 5 of the Directive), without this being treated as illegal advertising, been reflected in the legislation or practical guidance in the UK?

The supply of unlicensed medicinal products for individual patients in the UK is governed by paragraph 1 of Schedule 1 to SI 1994/3144, which permits supplies of unlicensed products in response to a *bona fide* unsolicited order, formulated in accordance with the specification of a doctor, dentist, supplementary prescriber, nurse independent prescriber or pharmacist independent prescriber and for use by his individual patients on his direct personal responsibility, in order to fulfil the special needs of those patients, provided certain conditions are met. The conditions are specified in paragraph 2 of Schedule 1 to SI 1994/3144, and include a requirement that "*No advertisement or representation relating to the relevant medicinal product is issued with a view to it being seen generally by the public in the UK, and that no advertisement relating to that product, by means of any catalogue or circular letter, is issued by, at the request or with the consent of, the person selling that product by retail or by way of wholesale dealing or supplying it in circumstances corresponding to retail sale, or the person who manufactures it and that the sale or supply is in response to a bona fide unsolicited order*".

This condition previously included price lists as prohibited advertisements, but following the decision in the *Ludwigs* case the restriction was deleted in August 2010 and accordingly holders of a licence permitting the manufacture, importation and/or distribution of unlicensed medicines may now issue price lists to healthcare professionals without first having received a *bona fide* unsolicited order.

2.6 May information be sent to institutions to enable them to plan ahead in their budgets for products to be authorised in the future?

The ABPI Code makes express provision for this (supplementary information to Clause 3.1), provided that certain conditions are met. In particular, the new medicine must represent a significant development (e.g. contain a new active substance or have a novel and innovative means of administration), and have significant budgetary implications; the information must be directed only towards those responsible for budgets and not to prescribers; and it must be limited to factual material. The information must not be in the style of promotional material. MHRA Guidance also acknowledges that such information may be provided "exceptionally".

2.7 Is it possible for companies to involve health professionals in market research exercises concerning possible launch materials for medicinal products as yet unauthorised? If so, what limitations apply? Has any guideline been issued on market research of medicinal products?

Under the ABPI Code, market research is defined as the collection and analysis of information and must be unbiased and non-promotional. The use made of such information and statistics may be promotional, but these two phases must be kept distinct. It is acceptable to enter into agreements with health professionals for *bona fide* consulting services, including market research activities. It would, in principle, be possible to conduct market research exercises concerning launch materials for products as yet unauthorised, but it is not permitted to use such activities as a platform for disguised promotion to health professionals. In this regard, it is crucial to define the objective of the market research, which will decide the number of healthcare professionals that it is reasonable to involve. Any materials used should be strictly non-promotional. It is preferable to use generic names where possible. The British Healthcare Business Intelligence Association has produced guidelines on market research in consultation with the ABPI entitled "The Legal and Ethical Framework for Healthcare Market Research".

3 Advertisements to Health Professionals

3.1 What information must appear in advertisements directed to health professionals?

Regulation 14 of SI 1994/1932 (reflected in Clause 4 of the ABPI Code) states that, with the exception of audio-visual advertisements and abbreviated advertisements, all advertisements to health professionals must contain essential information compatible with the SmPC and must contain the following:

- Marketing authorisation number.

- Name and address of marketing authorisation holder.
- Supply classification of medicinal product.
- Name of medicinal product and list of active ingredients immediately adjacent to the most prominent display of the name.
- One or more indications for use consistent with the terms of the authorisation.
- Succinct statement of entries in SmPC relating to side-effects, cautions and relevant contra-indications.
- Succinct statement of entries in SmPC relating to dosage, method of use and method of administration (where not obvious).
- Any warning which the licensing authority requires being included.
- The cost of the product.

Regulation 15 contains special rules for audio-visual advertisements. These must contain essential information compatible with the SmPC and refer to the particulars listed in the bullet points above. However, those particulars may be contained in written material made available to those viewing the advertisement.

Regulation 16 sets out special derogations for "abbreviated advertisements" (advertisements no larger than 420 square centimetres contained in a publication sent or delivered to health professionals). Such advertisements must contain essential information compatible with the SmPC and also the following:

- Name and address of marketing authorisation holder.
- Supply classification of product.
- Name of medicinal product and list of active ingredients immediately adjacent to the most prominent display of the name.
- A form of words which indicates that further information is available on request, or in the SmPC.

Regulation 17 states that the requirements in Regulations 14, 15 and 16 do not apply in the case of an advertisement which is a promotional aid if the advertisement consists solely of the name of the product or its international non-proprietary name or trademark (or, in the case of a registered homoeopathic medicinal product, the scientific name of the stock or stocks or its invented name), and is intended solely as a reminder. The ABPI Code prohibits many items given as promotional items in the past (e.g. coffee mugs, computer accessories, etc). The only promotional items expressly permitted are inexpensive notebooks, pens and pencils for use by health professionals and appropriate administrative staff attending scientific meetings and conferences and promotional meetings. Such promotional aids must not bear the name of any medicine or any information about medicines, but may bear the name of the company providing them.

Further guidance about prescribing information and other obligatory information is set out in the ABPI Code: Clause 4 (legibility and type size); and Clause 6 (journal advertising).

These rules also apply to international journals where these are produced in English in the UK (even if only a small proportion of their circulation is to a UK audience) and/or intended for a UK audience.

3.2 Are there any restrictions on the information that may appear in an advertisement? May an advertisement refer to studies not in the SmPC?

In Case C-249/09 *Novo Nordisk*, the CJEU concluded that Article 87(2) of the Directive prohibits the inclusion in advertising of claims that conflict with the SmPC, but that not all of the information contained in an advertisement need be identical to that in the SmPC, provided the claims are consistent with the information in the SmPC. Advertisements may, therefore, include additional claims, provided that these confirm or clarify (and are compatible with) the information set out in the SmPC. Any such additional information must also meet the various other requirements of the Directive, such as being presented objectively, faithfully and in such a way as to allow independent verification, and not being exaggerated, misleading or inaccurate. This reflects current practice in the UK. Clause 3.2 of the ABPI Code provides that the promotion of a medicine must be in accordance with the terms of its marketing authorisation and must not be inconsistent with the particulars listed in its SmPC.

3.3 Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional materials?

Regulation 9 of SI 1994/1932 prohibits the issue of advertisements to the general public containing any material which refers to a recommendation by scientists, health professionals, or persons who are neither of the above but who, because of their celebrity, could encourage the consumption of medicinal products. This limitation does not apply to medicines advertising to healthcare professionals.

3.4 Is it a requirement that there be data from any or a particular number of "head to head" clinical trials before comparative claims are made?

Controlled 'head to head' clinical trial data are not required to substantiate comparative claims, although the availability of such data will inevitably assist in demonstrating that statements are balanced and can be substantiated. Presentations of weak comparative data from individual studies may be judged misleading and all relevant data must be presented to ensure a fair and balanced comparison. Differences which do not reach statistical significance must not be presented in such a way as to mislead. Before statistical information is included in promotional material it must have been subjected to statistical appraisal.

The MHRA has advised that, where secondary end-points are being used to promote a product, primary end-point data and the limitations of the data must be included (MHRA MAIL 148 of March/April 2005).

Hanging comparisons are not acceptable, i.e. those describing a medicine as "better" or "stronger" without providing a comparator (Supplementary Information to Clause 7.2 of the ABPI Code).

3.5 What rules govern comparative advertisements? Is it possible to use another company's brand name as part of that comparison? Would it be possible to refer to a competitor's product which had not yet been authorised in the UK?

Comparator advertisements are permitted, provided that they are accurate, fair, balanced, objective, unambiguous, based on an up-to-date evaluation of the evidence and reflect the evidence clearly. They must not be misleading (Regulation 3A of SI 1994/1932; Clause 7 of the ABPI Code). In such a case, it is possible to use another company's brand name without its permission, provided that no unfair advantage is taken of the reputation of the brand name or the other company. Disparaging references to other products are prohibited (Clause 8 of the ABPI Code).

Advertising material referencing a competitor's product, which has not been authorised in the United Kingdom, may be characterised as promoting an unlicensed medicine contrary to Regulation 3 of SI 1994/1932 and Clause 3 of the ABPI Code.

3.6 What rules govern the distribution of scientific papers and/or proceedings of congresses to doctors?

The distribution of conference proceedings, abstract booklets, meeting reports or a slide set following a scientific congress or conference may constitute promotion depending upon the circumstances and the content of such information. To the extent such information relates to a medicinal product, provision on an unsolicited basis would be considered to constitute a promotional activity and, therefore, the general requirements regarding promotional materials should be complied with. Reprints of articles in journals which have not been refereed must not be provided unless in response to a request. Placing documents on exhibition stands amounts to an invitation to take such materials, i.e. it solicits the request. When providing an unsolicited reprint of an article about a medicine, it should be accompanied by prescribing information (Clause 10.1 of ABPI Code).

All material relating to medicines and their uses whether promotional or not, which is sponsored by a pharmaceutical company, must identify that fact sufficiently prominently so that the reader or recipient is aware of the position from the outset (Clause 9.10 of the ABPI Code).

3.7 Are "teaser" advertisements permitted that alert a reader to the fact that information on something new will follow (without specifying the nature of what will follow)?

While there is no specific reference to such advertisements in the Regulations, they are prohibited in the UK by Clause 9 of the ABPI Code.

4 Gifts and Financial Incentives

4.1 Is it possible to provide health professionals with samples of products? If so, what restrictions apply?

Under Regulation 19 of SI 1994/1932 (reflected in Clause 17 of the ABPI Code), free samples are permitted, provided certain conditions are met. Samples must not be provided as an inducement to prescribe or supply any medicine. In particular, they must only be provided to persons qualified to prescribe medicinal products and they must be provided to enable those persons to acquire experience in dealing with the product. No samples of controlled products may be supplied. In addition:

- Samples must be supplied on an exceptional basis only.
- A limited number of samples of each product may be supplied in any one year to any one recipient (the ABPI Code states that this should not exceed ten samples).
- The 2008 version of the ABPI Code introduced a prohibition on the supply of samples which have been on the UK market for more than 10 years; this restriction is maintained in the 2011 edition.
- Samples must only be supplied in response to a written, signed and dated request.
- The supplier must maintain an adequate system of control and accountability.
- Samples must be no larger than the smallest presentation available for sale.
- Samples must be marked with wording indicating that they are free medical samples and are not for resale.
- A copy of the SmPC must accompany samples.

4.2 Is it possible to give gifts or donations of money to medical practitioners? If so, what restrictions apply?

The provision of gifts is possible in limited circumstances under Regulation 21 of SI 1994/1932 if they do not constitute an inducement to a healthcare professional to prescribe or supply any medicine. Such gifts must be inexpensive and relevant to the recipient's work.

The ABPI Code now prohibits many of the traditional forms of promotional aid, such as coffee mugs and calendars, items for use in clinics such as surgical gloves or tissues, or toys and puzzles for children (Supplementary Information to Clause 18.1).

Items intended to be passed on to patients can be provided to health professionals if these are part of a patient support programme, the details of which have been appropriately documented and certified in advance. They must cost no more than £6, excluding VAT, and the perceived value to the health professional and the patient must be similar. They must directly benefit patient care.

In limited circumstances, patient support items can be provided to health professionals when they are not to be passed to patients for them to keep (e.g. devices to assist patients to learn how to self-inject).

The only items that can be provided to health professionals for them to keep are the notebooks, pens and pencils for use at *bona fide* meetings and conferences mentioned in question 3.1 above.

In connection with offences under Regulation 21, the law relating to bribery in the UK has been significantly modernised by the Bribery Act 2010, which entered into force on 1 July 2011. In addition to the ongoing corporate liability for employees engaging in bribery, companies which fail to put in place adequate systems for avoiding conduct by its employees and associated persons amounting to bribery may also be guilty of an offence.

Closely interlinked with the Bribery Act, the Procurement Directive 2004/18/EC provides for a sanction of debarment from public procurement to any candidate who has been convicted of an offence, of which the contracting authority is aware. While Member States were able to include a derogation in their own legislation, which allowed for the right to override this exclusion where it was in the general interest, there is not such a derogation in the UK. With its implications on public procurement the Bribery Act has far-reaching compliance consequences for companies, even those with a minimal presence in the UK. The UK government has indicated that debarment from public procurement is discretionary where a company is convicted of an offence of failing to prevent bribery by an associated person. Debarment is still mandatory if a company is convicted of an offence of active bribery, including bribery of a foreign public official.

Donations of money to medical practitioners are not permitted, although donations to reputable charities may be acceptable provided that any associated action required of the healthcare professional is not inappropriate (e.g. the offer of a donation to charity in return for granting interviews with medical representatives). The use of competitions, quizzes and suchlike, and the giving of prizes, are unacceptable methods of promotion (Supplementary Information to Clause 18.1 of the ABPI Code).

In addition, the National Health Service has published general Guidelines on Commercial Sponsorship, setting out ethical standards which all health professionals must observe. For

example, National Health Service staff and contractors must refuse to accept gifts, benefits, hospitality or sponsorship of any kind which might reasonably be seen to compromise their personal judgment or integrity. In addition, gifts, benefits and sponsorships must be declared in a register.

4.3 Is it possible to give gifts or donations of money to institutions such as hospitals? Is it possible to donate equipment, or to fund the cost of medical or technical services (such as the cost of a nurse, or the cost of laboratory analyses)? If so, what restrictions would apply?

The ABPI Code (Clause 18.4) states that medical and educational goods and services can be provided where the gift or donation is intended to enhance patient care or to benefit the National Health Service and maintain patient care. However, such a gift or donation must not be offered as an inducement to an individual prescriber or group of prescribers to prescribe or use any particular medicine. They must not be provided to individuals for their personal benefit. Items donated may bear the company name, but cannot bear a product name.

The supplementary information to Clause 18.4 of the ABPI Code contains detailed guidelines on the provision of medical and educational goods and services to the National Health Service. For example, the recipient of any services must be provided with a written protocol setting out the details of the arrangement and, while a company may sponsor a nurse, the nurse must not be used to promote the company's products. These provisions are endorsed in the MHRA Guidance.

The supplementary information to Clause 18 of the ABPI Code also explains the role that medical/sales representatives can play in the provision of medical and educational goods and services. The underlying principle is that there must be no linkage of any description between the provision of goods and services and promotional activities. The ABPI Code recommends that companies should inform relevant parties (e.g. NHS Trusts, primary care organisations) of their activities, particularly where the provision of medical and educational goods and services would have budgetary implications for the parties involved.

The Department of Health encourages "joint working" between the NHS and the pharmaceutical industry (e.g. through interaction with those responsible for delivering and administering healthcare) in ways compatible with the ABPI Code. Clause 18.5 of the ABPI Code addresses joint working in some detail. An executive summary of a joint working agreement must be made public in relation to joint working projects started on or after 1 May 2011 or ongoing on that date. The ABPI Code also deals with outcome or risk sharing agreements, patient access schemes and package deals.

4.4 Is it possible to provide medical or educational goods and services to doctors that could lead to changes in prescribing patterns? For example, would there be any objection to the provision of such goods or services if they could lead either to the expansion of the market for or an increased market share for the products of the provider of the goods or services?

Where relevant medicinal products are being promoted, the free provision of medical or educational goods and services to doctors (or other persons qualified to prescribe or supply relevant medicinal products), which provide a personal benefit to them, constitutes an inducement to prescribe. This is a criminal offence, committed by both the company and individual who make the offer, and by the health professional who received the inducement. The provision of medical and educational goods and services must, therefore, be kept entirely separate from promotional activities and this principle should be reinforced in the training of any sales representatives who visit prescribers to whom such services may be offered. Prescribers must not, for example, be selected as potential recipients of an offer of medical and educational services on the basis of their prescribing habits.

Where medical or educational goods and services improve awareness of a particular disease or assist in diagnosis, this may expand the overall market for relevant treatments without promoting any particular medicine. The ABPI Code confirms at the supplementary information of Clause 1.1 that such market extension activities will be acceptable if conducted in accordance with the ABPI Code. However, if the provision of such services to prescribers leads, or appears to lead, to a change in prescribing habits, there is a risk that the PMCPA will draw an adverse conclusion about a company's and the prescriber's motives, in the absence of clear evidence to the contrary.

The ABPI Code now obliges companies to make publicly available details of medical and educational goods and services in the form of donations, grants and benefits in kind provided to institutions, organisations or associations comprised of health professionals.

4.5 Do the rules on advertising and inducements permit the offer of a volume related discount to institutions purchasing medicinal products? If so, what types of arrangements are permitted?

Both the Regulations and the ABPI Code state that measures or trade practices relating to prices, margins and discounts are permitted, provided that these are of a type that was in regular use by a significant proportion of the pharmaceutical industry in the UK on 1 January 1993. No official guidance is available on precisely what arrangements would qualify, although the MHRA Blue Guide states that "these are primarily financial terms and normally cover cash discounts or equivalent business discount schemes on purchases of medicinal products, including volume discounts and similar offers such as "14 for the price of 12", provided they are clearly identified and invoiced".

In the case of over-the-counter medicines, while multiple purchase promotions for consumers are not illegal, the MHRA strongly discourages offers relating to analgesics, because of the risk of overdose.

4.6 Is it possible to offer to provide, or to pay for, additional medical or technical services or equipment where this is contingent on the purchase of medicinal products? If so, what conditions would need to be observed?

This is not possible.

4.7 Is it possible to offer a refund scheme if the product does not work? If so, what conditions would need to be observed? Does it make a difference whether the product is a prescription-only medicine, or an over-the-counter medicine?

While such arrangements are uncommon, the concept of patient access programmes agreed between industry and the Department of Health (with input from the National Institute for Health and Clinical Excellence) has been accepted in certain circumstances and a number of such schemes have been introduced. The ABPI Code confirms that patient access schemes are acceptable in principle, but they must be carried out in conformity with its requirements.

The 2009 Pharmaceutical Price Regulation Scheme describes patient access schemes as schemes proposed by a pharmaceutical company and agreed with the Department of Health (with input from the National Institute for Health and Clinical Excellence) in order to improve the cost-effectiveness of a medicine and enable patients to receive access to cost-effective innovative medicines.

They are categorised as: financially based schemes (discounts or rebates are offered depending on number of patients treated, the response of patients treated or the number of doses required); or outcome based schemes (where the price of the product may be increased or a rebate paid in the light of additional evidence collection, or formal risk-sharing schemes where price adjustments will be made based on outcomes obtained relative to those anticipated in the terms of the scheme).

4.8 May pharmaceutical companies sponsor continuing medical education? If so, what rules apply?

Companies may sponsor Continuing Medical Education (CME) programmes for health professionals, but any such support must in all cases be non-promotional and must comply with the rules of the appropriate Royal College responsible for CME. An application should be made to the relevant Royal College for accreditation of a meeting for CME. The fact that a meeting or course is approved for CME does not mean that the arrangements are automatically acceptable under the ABPI Code. Any company involvement must be reviewed to ensure that it complies with the ABPI Code, particularly the provisions in relation to hospitality. A company may provide proposals to CME organisers for programme content, speaker and venue selection. In addition, subject to obtaining the agreement of the event organiser, a company may make available information about its own products. A company may pay registration fees for health professionals to attend a CME event and, subject to the restrictions contained in section 5 below, may also provide travel and subsistence expenses associated with attendance at the event. Health professionals may not, however, be paid an honorarium merely for attendance. There is generally no bar to the presence of sales representatives at a CME event.

5 Hospitality and Related Payments

5.1 What rules govern the offering of hospitality to health professionals? Does it make a difference if the hospitality offered to those health professionals will take place in another country?

This is governed by Regulation 21 of SI 1994/1932 (reflected in Clause 19 of the ABPI Code). Hospitality must be strictly limited to the main purpose of the event and must be secondary to the purpose of the meeting i.e. subsistence only. Nobody other than a health professional may be offered hospitality. The ABPI Code states that exceptionally, it may be possible to offer hospitality to appropriate administrative staff, but it is not possible, for example, to include spouses (unless they are also health professionals).

The rules apply to UK health professionals offered hospitality, whether this takes place in the UK or overseas.

5.2 Is it possible to pay for a doctor in connection with attending a scientific meeting? If so, what may be paid for? Is it possible to pay for his expenses (travel, accommodation, enrolment fees)? Is it possible to pay him for his time?

Clause 19 of the ABPI Code allows the payment of reasonable travel costs, accommodation and enrolment fees by a company to enable a delegate to attend a scientific meeting, although the payment of such expenses in relation to persons accompanying the delegate is not permitted. Companies should only offer or provide economy air travel to delegates, although delegates may organise and pay for the genuine difference between economy travel and business class or first class. The payment of compensation to healthcare professionals simply for attending a meeting is not permitted, although if a delegate is also a speaker, a reasonable honorarium may be paid.

5.3 To what extent will a pharmaceutical company be held responsible by the regulatory authorities for the contents of and the hospitality arrangements for scientific meetings, either meetings directly sponsored or organised by the company or independent meetings in respect of which a pharmaceutical company may provide sponsorship to individual doctors to attend?

Where a company has sponsored a meeting it is responsible for ensuring that all the arrangements (meeting content and hospitality) comply with the provisions of the ABPI Code.

Where a company sponsors an individual doctor to attend a meeting organised by a third party, the company will be responsible for ensuring that the level of sponsorship is consistent with the ABPI Code. A pharmaceutical company is not, in principle, responsible for the contents of a meeting organised by an independent third party if the company has not had any involvement or influence over such content and can demonstrate that this is the case.

5.4 Is it possible to pay doctors to provide expert services (e.g. participating in focus groups)? If so, what restrictions apply?

It is possible to pay doctors to provide expert services, including travel costs and payment for time spent attending meetings. However, the arrangements must relate to genuine consultancy or other services and a written contract should be agreed before the services commence. The number of doctors involved in such activities must be limited and there should be an objective reason linked to the interest or expertise of the particular doctor for including him. Clause 20 of the ABPI Code obliges companies to include provisions in their contracts with consultants, requiring the consultant to declare the consultancy when writing or speaking about matters relating to the agreement or the company. Pharmaceutical companies must make publicly available details of the fees paid to consultants in the UK. The information which must be disclosed is the total amount paid in a calendar year to all of the consultants who have provided services. The total number of consultants must be given. The names of the consultants need not be disclosed.

5.5 Is it possible to pay doctors to take part in post marketing surveillance studies? What rules govern such studies?

A pharmaceutical company may pay compensation to doctors or

institutions conducting non-interventional post-marketing experience or surveillance programmes. Clause 13 of the ABPI Code provides that all prospective studies which involve the collection of patient data must have a genuine scientific purpose and must not be used as a mechanism for promoting the company's products. Each study must be conducted pursuant to a protocol and be the subject of a contract between the health professional and/or the institute at which the study tales place, and the pharmaceutical company. Ethics committee and regulatory authority approvals may be required. Institutions and investigators must be selected based upon their experience, ability to meet the enrolment requirements and must adhere to the principles of good clinical practice. A health professional's or institution's history of, or potential for, purchasing or prescribing company products may not be taken into account in the selection of investigators or institutions. Compensation may be paid on a per patient basis, but must be reasonable and commensurate with the services to be performed. An investigator should not be compensated for performing a medical evaluation that he or she would have performed regardless of his or her patient's participation in the clinical trial.

5.6 Is it possible to pay doctors to take part in market research involving promotional materials?

As stated in response to question 2.6 above, it is acceptable to enter into agreements with health professionals for *bona fide* consulting services, including market research activities, but such activities may not be used as a platform for disguised promotion to health professionals. The name of the company does not need to be revealed in market research material; it is sufficient to state that it is sponsored by a pharmaceutical company. Appropriate compensation may be paid to respondents for their time, however, inducements which could influence respondents' opinions or behaviour must not be offered. The limitations imposed by Clause 20 of the ABPI Code do not apply where market research is limited (e.g. one off telephone interview or mailing), as long as the remuneration is minimal.

5.7 Is there a requirement in law and/or self-regulatory code for companies to make publicly available information about donations, grants, benefits in kind or any other support provided by them to health professionals, patient groups or other institutions? If so, what information should be disclosed, from what date and how?

Clause 18.6 of the ABPI Code requires that the provision of medical and educational goods and services in the form of donations and grants to institutions, organisations or associations that are comprised of health professionals and/or that provide healthcare or conduct research be made publicly available.

All donations and grants made in 2012 and each calendar year thereafter must be disclosed. Disclosure must be in the calendar year following that in which donations and grants were provided and the information must be made public within three calendar months of the end of the company's financial year. Local operating companies must take reasonable steps to disclose donations and grants provided by their overseas affiliates, head offices in the UK or overseas and UK based European offices.

Companies are also encouraged, but not obliged to, make publicly available information about any benefits in kind provided by them which are covered by Clause 18.6 of the ABPI Code.

6 Advertising to the General Public

6.1 Is it possible to advertise non-prescription medicines to the general public? If so, what restrictions apply?

Non-prescription medicines may be advertised to the general public. Regulation 9 of SI 1994/1932 sets out certain conditions which must be complied with. The advertisement must not:

- Give the impression that a medical consultation is not necessary.
- Suggest that the effects of the medicine are guaranteed, without side effects, or better than or equivalent to another medicine or treatment.
- Suggest that taking the medicine will enhance health.
- Suggest that health may be adversely affected by not taking the medicine.
- Be directed to children.
- Include a recommendation by a health professional or well-known person if this could encourage the consumption of the medicine.
- Suggest that the product was a food, cosmetic or other consumer product.
- Suggest that the safety or efficacy of the product was due to its natural status.
- Might, by use of a case history, lead to erroneous self-diagnosis.
- Refer in improper, alarming or misleading terms, to claims of recovery.
- Use improper, alarming or misleading representations of the human body.

It is now possible to refer to the fact that the product has a marketing authorisation. Further guidance on the interpretation of these provisions is contained in the PAGB Code.

6.2 Is it possible to advertise prescription-only medicines to the general public? If so, what restrictions apply?

This is prohibited by Regulation 7 of SI 1994/1932.

6.3 If it is not possible to advertise prescription-only medicines to the general public, are disease awareness campaigns permitted, encouraging those with a particular medical condition to consult their doctor, but mentioning no medicines? What restrictions apply?

Guidance on this issue has been provided by the MHRA (the Disease Awareness Campaign Guidelines included at Annex 3 to the Blue Guide) and by the ABPI (Clause 22 of the ABPI Code).

Non-promotional information regarding prescription-only medicines may be made available to the public in response to a direct enquiry from an individual or journalist and in certain other circumstances. Such information must be factual and balanced. Statements must not be made for the purpose of encouraging members of the public to ask their doctors to prescribe a particular medicine.

The ABPI Code states that it is good practice to make certain reference material available to the public, including the public assessment reports (UK or European), summaries of product characteristics and package leaflets.

Disease awareness campaigns are permitted. It is important that the purpose of the campaign is to increase awareness of a disease and

to provide health education information on that disease and its management. While it may involve the discussion of treatment options, it must not promote the use of a particular medicinal product. Disease awareness campaigns where there is only one treatment option, or only one medicine in a particular class, require particular care. The provision of advice or personal medical matters to individual members of the public is not permitted.

Information on prescription-only medicines may also be provided to financial institutions and shareholders, provided it is factual and balanced.

6.4 Is it possible to issue press releases concerning prescription-only medicines to non-scientific journals? If so, what conditions apply?

This is possible, provided the information is of genuine scientific interest and not promotional in tone. It must not encourage members of the public to ask their doctor to prescribe a particular product. Use of the brand name should be kept to the minimum. Press releases must be certified as compliant with the ABPI Code before being issued.

6.5 What restrictions apply to describing products and research initiatives as background information in corporate brochures/Annual Reports?

Guidance on this issue has been provided by the MHRA and the ABPI (Clause 22 of the ABPI Code). Companies may provide corporate advertising and financial information to UK businesses and financial press to inform shareholders, the Stock Exchange etc. This information should be drafted with the view of keeping shareholders and the like fully aware of developments which may be material to their UK share price. Business press releases and corporate brochures should identify the commercial importance of the information and should be factual and balanced. The ABPI Code alerts companies to the fact that a non-promotional item can be used for a promotional purpose and therefore come within the scope of the ABPI Code. Corporate information should always be examined to ensure that it does not contravene the ABPI Code or the relevant statutory requirements, but is not subject to the certification requirements.

6.6 What, if any, rules apply to meetings with and funding of patient support groups, including any transparency requirement as regards the recording of donations and other support in corporate reports?

Clause 23 of the ABPI Code specifically addresses relationship with patient organisations. Pharmaceutical companies may interact with patient organisations or user organisations to support their work. However, such involvement must be transparent and all arrangements must comply with the ABPI Code. The limitations on the hospitality to be provided to healthcare professionals (Clause 19 of the ABPI Code) are also applicable to patient organisations.

Each company must make publicly available, at national or European level, a list of patient organisations to which it provides financial support and/or significant indirect/non-financial support, which must include a description of the nature of the support that is sufficiently complete to enable the average reader to form an understanding of the significance of the support. A list of organisations being given support, including the monetary value of the support, must be made publicly available by the end of the first quarter of 2013.

Companies working with patient organisations must have in place a written agreement setting out exactly what has been agreed, in relation to every significant activity or ongoing relationship. The written agreement should set out the activities agreed and the level of funding and refer to the approval process for each party. Material relating to working with patient organisations must be certified in advance by two persons on behalf of the company (Clause 14.3 of the ABPI Code).

There are other codes and guidelines applicable to specific patient groups, such as the Long Term Medical Conditions Alliance guidelines. In addition, patient organisations themselves are likely to be covered by the rules of the Charity Commission (the regulator and registrar for charities in England and Wales), as well as their own codes.

7 The Internet

7.1 How is Internet advertising regulated? What rules apply? How successfully has this been controlled?

The PMCPA published guidance on digital communications in April 2011. This makes it clear that the same rules apply to digital communications as for other forms of advertising. Promotional material directed to a UK audience via the Internet is, therefore, subject to the ABPI Code. However, as a matter of practice, enforcement remains an issue as far as the regulators are concerned, as they are only able to enforce against entities with a presence in the jurisdiction.

Clause 24 of the ABPI Code indicates that the PMCPA will take action where the advertising has been placed on the Internet by or with the authority of a UK company and makes reference to the availability or use of a product in the UK. The PMCPA has upheld a number of complaints under this provision.

The MHRA Guidance states that the UK rules will apply to "material posted on UK websites and/or aimed at the UK audience" and a significant proportion of complaints upheld by the MHRA relate to internet advertising, relating, in particular to promotion in the UK of an unlicensed product and advertising of prescription only medicines to the public. Where companies include links from their UK site to their websites serving other countries, this should be made clear to UK users. Users should not need to access non-UK sites to obtain basic information about the company's products.

7.2 What, if any, level of website security is required to ensure that members of the general public do not have access to sites intended for health professionals?

The MHRA Guidance states that websites aimed at health professionals "should ideally be access restricted" and that the public should not be encouraged to access material which is not intended for them. The Supplementary Information to Clause 24.1 of the ABPI Code provides that unless access to promotional material about prescription-only medicines is limited to health professionals and appropriate administrative staff, a pharmaceutical company website or a company sponsored website must provide information for the public, as well as promotion to health professionals with the sections for each target audience clearly separated and the intended audience identified. The rationale behind this requirement is to avoid the public needing to access material for health professionals unless they choose to.

7.3 What rules apply to the content of independent websites that may be accessed by link from a company sponsored site? What rules apply to the reverse linking of independent websites to a company's website? Will the company be held responsible for the content of the independent site in either case?

Although Clause 24.6 of the ABPI Code states that sites linked via company sites are not necessarily covered by the ABPI Code, a company will be responsible for ensuring that material on a site linked from its website complies with the ABPI Code and laws relating to the advertising and promotion of medicines. On that basis, referring health professionals or patients to a website giving information about an unlicensed indication may be viewed as promoting that unlicensed indication. If an independent website provides a link to a company website, the company will only be responsible for any breach of the ABPI Code which might arise as a result of the linkage (e.g. linking a site accessible by the general public to a site for health professionals) if the link has been established with its knowledge and consent.

7.4 What information may a pharmaceutical company place on its website that may be accessed by members of the public?

Companies are encouraged to place on their website reference material that is intended to act as a library resource for members of the public giving information relating to prescription-only medicines which have marketing authorisations. It is considered good practice to provide as a minimum regulatory information comprising the Summary of Product Characteristics (SmPC), the Package Leaflet (PIL) and the Public Assessment Report (EPAR or UKPAR), where such a document exists. Reference information may include the registration studies used for marketing authorisation applications and variations and any other studies, published or not, including those referred to in the SmPC, PIL, EPAR or UKPAR or available on clinical trial databases. Reference information may also include material supplied for health technology assessments, medicines guides and information about diseases. Reference information must represent fairly the current body of evidence relating to a medicine and its benefit/risk profile.

8 Developments in Pharmaceutical Advertising

8.1 What have been the significant developments in relation to the rules relating to pharmaceutical advertising in the last year?

The main case law developments in the last year revolved around the distinction between advertising and providing information to patients on prescription medicines. The *Novo Nordisk* and *MSD* cases have provided useful clarifications on when communications to patients will breach the advertising rules. The MHRA has continued to review complaints according to its current procedures, i.e. by examining the purpose to the information being presented, its public health aspect and its impact on the prescription, sale, supply and consumption of the medicinal product. The MHRA's project to review and consolidate medicines legislation is still ongoing. This has included rewriting the Advertising Regulations. The major changes have been to update the definition of advertising to reflect that in the Directive rather than the original definition in the Medicines Act, and a review of wording to ensure that modern digital communications media are adequately covered. The second phase of this project is to review the legislation and determine whether changes could be made to simplify and reduce the regulatory burden where this is possible within the constraints of European law. Two areas of advertising have been identified, sanctions and review of proposed determinations. The MHRA conducted a formal public consultation on all the proposed changes during 2011, and anticipates that the draft Regulations will come into force in July 2012.

The PMCPA has also developed additional guidance on how companies can communicate with health professionals about prescription-only medicines using digital media. This guideline was published on 1 April 2011.

8.2 Are any significant developments in the field of pharmaceutical advertising expected in the next year?

The most significant development in the next year will be the entry into force of the consolidated medicines legislation.

In preparation for the implementation of the new UK legislation, the MHRA is reviewing the Blue Guide. The most recent edition was published in 2005 and several pieces of stand-alone guidance have been issued since that time. The MHRA plans to add in guidance that addresses what is permissible when using new digital media to communicate about medicines, as well as guidance on abbreviated advertisements, unlicensed use, the provision of information to the public and discussions with policy decision makers before marketing authorisations are granted. The revised version is expected to be published with the new UK legislation in July 2012.

The MHRA is also considering whether legal changes should be made to support the ABPI Code restrictions on promotional aids and in support of the recommendations of the 2009 report by the Royal College of Physicians, "Innovating for Health", which recommended an end to all industry gifts for doctors and their supporting staff.

In February 2011, the MHRA issued a draft guideline designed to provide clarity about the rules governing the advertising of homeopathic medicines licensed under the three regulatory schemes available.

On 10 February 2012 the European Commission published an amended proposal on proposed changes to the European legislation regarding the provision of information to patients. The revised proposals distinguish between information that marketing authorisation holders are required to provide (package leaflet, SmPC, etc.), and information that they may choose to provide (complementary instructions for use, details of price and packaging changes, etc.). They propose granting the EMA competency to vet such materials in relation to centrally authorised products, and also address the channels through which such materials may be provided. Predictably, there is a diversity of opinions on the revised proposals across Member States, and it is expected that discussions may continue for some time.

The MHRA sought agreement from the Heads of Medicines Agencies to set up an informal forum for the teams responsible for regulation of medicines advertising in each Member State, to exchange relevant information about their work. This new forum is expected to be operational in the near future.

8.3 Are there any general practice or enforcement trends that have become apparent in the UK over the last year or so?

Over the last year the number of advertising complaints received by the MHRA remained broadly static. As in previous years, a high proportion of complaints received related to advertising of

botulinum toxin products and other prescription-only medicines to the public by cosmetic clinics and service providers such as online pharmacies. A large number of these complaints originated from competitors who had themselves been subject to MHRA action and wished to ensure a level playing field.

8.4 Has your national code been amended in order to implement the 2011 version of the EFPIA Code on the promotion of prescription-only medicines to, and interactions with, healthcare professionals and the 2011 EFPIA Code on relationships between the pharmaceutical industry and patient organisations 2011 and, if so, does the change go beyond the requirements of the EFPIA Codes or simply implement them without variation?

The 2012 ABPI Code has implemented the changes to the 2011 EFPIA Code without significant variation. Clause 17.2 of the ABPI Code provides that no more than four samples of a particular new medicine may now be provided to an individual health professional during the course of a year, and then for no longer than two years after that health professional first requested samples of it. 'New medicine' is defined in the supplementary information to Clause 17.2 as a product for which a new marketing authorisation has been granted, either following the initial application or following an extension application for a new indication that includes new strengths and/or dosage forms.

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